

## REMARKS

Claims 1-8, 11 and 13-17 are pending in the current application and claims 9 and 12 are cancelled without prejudice or disclaimer. In a final Office Action dated 12 November 2008, The Examiner rejects claims 1-9, 11, and 12. Subsequently an in person interview was held on 11 December 2008 between the Examiner and Applicant's Representative of which a summary is included herein. In reply to the Examiners rejections, the Amendment included herein is submitted along with the present Remarks. Entry and consideration hereof is respectfully requested. The Examiner's particular rejections are now addressed in turn.

Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner cites a possible confusion regarding the wording discrepancy between "comprises" in claim 4 and "on" in claim 5. The amendment herein corrects claim 4 to recite, inter alia,

"further comprising at least two finger members on the piston" (Emphasis Added)

Thus, it is Applicant's belief that the Examiners 35 U.S.C. 112, second paragraph rejection is overcome. Withdrawal of the rejection is respectfully requested.

Claims 1-5 and 9 are rejected as being anticipated under 35 U.S.C. 102(b) by U.S. Patent No. 6,186,960 to Tripp. Herein, claim 1 is amended to further distinguish the claims from Tripp and the remaining cited references and the rejection of claim 9 is moot in view of the cancellation thereof. Specifically, claim 1 is now revised to recite a blood collection device comprising, inter alia,

"wherein the needle holder contains an annular ring with at least two finger members extending therefrom that engage relative to the housing to retain the needle holder to the housing, each finger member being deflectable between a locking position where the finger member retains the needle holder to the housing, and a release position where the needle holder can be retracted into the housing." (Emphasis Added)

A general example of the abovementioned claim element can be found in Applicant's Figure 6A and 6B. Here needle holder 1B comprises a nosepiece 2 including *an annular ring with at least two finger members 2B extending therefrom* for retaining needle holder 1B onto the housing 46. See specification at: page 12, lines 4-19; page 13, lines 20-32; and page 14, lines 1-14. In this example, the finger members 2B are deflectable between a locking position (Figure 6A) and a release position (Figures 5 and 6B). *Id.* In the locking position, the nosepiece 2 is retained to the housing 46; in the release position, the nosepiece 2 is retracted into the housing 46 by a vacuum action. *Id.*

Referring back to the claims, Applicant respectfully submits that the above quoted limitation of claim 1 is simply not found in the Tripp reference. Instead, Tripp teaches a medical collection tube holder 10 having a detachable needle port hub 14 which is retained within a body 12 of the tube holder 10 by a hub release ring 16. Col. 4, line 50 through col. 5, line 5. To release the detachable needle port hub 14, an evacuated accessory 18 is inserted into the tube holder body 12 and pressed against the hub 14. By doing so, the hub release ring 16 is pushed off the needle port hub 14 and into an annular channel 42. Col. 6, lines 20-44; Figures 5-7. The needle hub 14 is thus liberated from the tube holder body 12 and is permitted to withdraw into the evacuated accessory 18.

Clearly, Tripp does not disclose a needle holder which “contains *an annular ring with at least two finger members extending therefrom* that engage relative to the housing to retain the needle holder to the housing”, as recited in Applicant's claim 1. To the contrary, as discussed immediately above, Tripp utilizes a hub release ring 16. Tripp clearly describes and illustrates the hub release ring 16 as an annular member which extends around the needle hub 14. This release ring 16 is not at all analogous to the recited “annular ring with at least two finger members extending therefrom”.

Furthermore, Tripp does not disclose “each finger member being deflectable between a locking position where the finger member retains the needle holder to the housing, and a release position where the needle holder can be retracted into the housing”, as recited by claim 1. The hub release ring 16 of Tripp does not include the recited finger members and the ring itself is simply not deflectable between varying

positions. Instead, as described, the ring 16 is pushed off of the needle hub 14 into the annular channel 42.

It is established that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As expressed above, every element of amended claim 1 is NOT found in Tripp, thus the reference fails to anticipate the claim.

Applicant notes that this amendment to claim 1 and corresponding argument were presented to the Examiner in the interview of 11 December 2008. Therein, the Examiner agreed expressed agreement that this amendment and argument overcame the Tripp patent. Reference is made to the Interview Summary above at page 2.

For at least these reasons, reconsideration and withdrawal of the relevant section 102 rejection of claim 1 is requested.

Claims 2-5 and 11 depend from novel claim 1 and are thus correspondingly novel; reconsideration and withdrawal of the relevant section 102 rejections is requested.

The rejection of claim 12 is moot in view of the cancellation thereof.

Claim 6 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Tripp in view of U.S. Patent No. 5,000,736 to Kaufhold et al. However, Kaufhold et al. does not remedy the deficiencies of Tripp. That is, Kaufhold does not disclose a needle holder having an annular ring with at least two deflectable finger members extending therefrom, as recited by Applicant. To the contrary, Kaufhold utilizes a hub 16 with thin walled portions configured to allow rupture of the hub 16 to affect releasement of the hub 16 from the interior of a syringe barrel 12. Accordingly, claim 6 is novel and nonobvious for the reasons expressed above with respect to claim 1. Moreover, Kaufhold as combined with Tripp does not render obvious the presently amended claim 1.

Claims 7 and 8 depends from novel claim 6 and is thus correspondingly novel; reconsideration and withdrawal of the relevant section 103 rejection is requested.

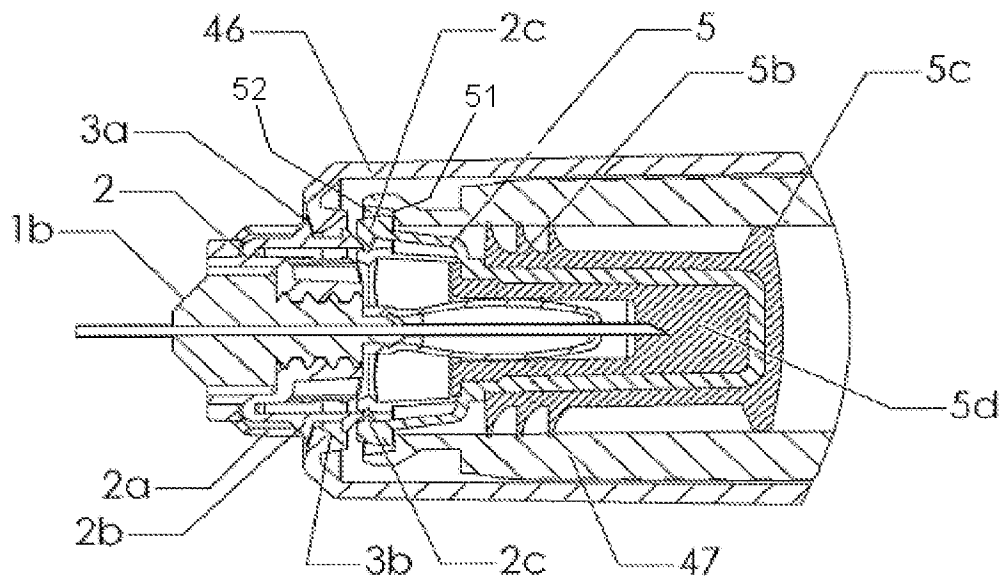
All of the rejections are herein addressed and overcome by the current amendments and remarks. No new matter is added herein as support is found throughout the originally filed specification. The application is now believed to be in condition for allowance. Prompt issuance of Notice of Allowance is respectfully requested.

Additionally, an IDS statement has been included with this amendment to formally introduce US Patent No. 5,658,257 to Ryles, discussed in the recent Examiner interview. However, Ryles disclosure generally deals with a syringe device, while Applicant's invention concerns a blood collection device. There are many differences between these two general device types. For example, a blood collection device must include a double needle, a piston made of pierceable material, and an entirely independent needle retraction device inserted after blood collection. Thus, due to the many structural differences one skilled in the art would not consider using the teachings of a syringe device towards the production of a blood collection device.

However, in light of Ryles teachings Applicant's invention is still novel and unobvious. Figures 6a and 6b, as amended herein, now include reference numerals 51 and 52 to identify novel elements of Applicant's invention. In addition, the specification has been amended herein to discuss reference numerals 51 and 52. Finally, claim 1 has been amended herein to distinguish the claim from Ryles. Specifically, claim 1 recites blood collection device comprising, inter alia,

“wherein each of the at least two engagement means is at least partially housed in a recess in an inner surface of the needle retraction device prior to the release of the needle holder from the housing.” (Emphasis Added)

A general example of this claim feature can be found in Applicant's amended Figure 6A, shown below.



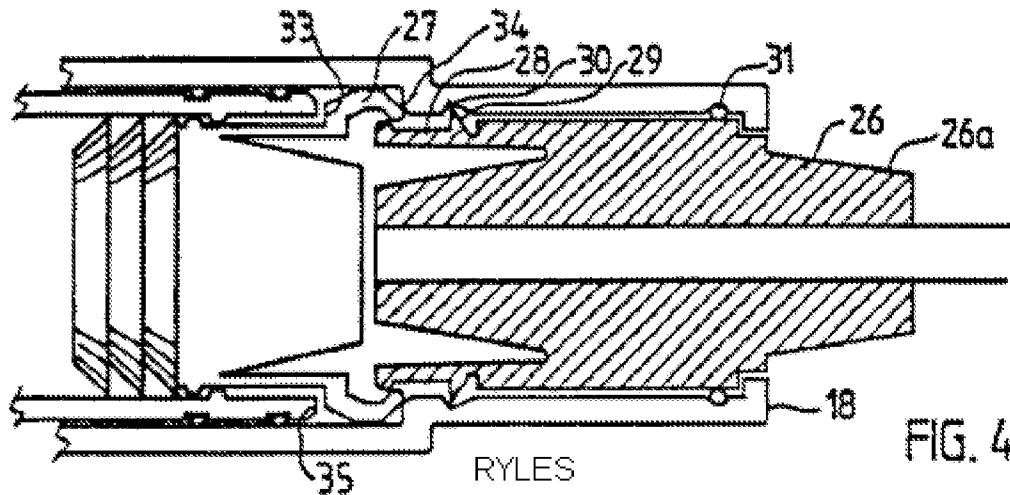
**FIG 6A**

As exemplified above, engagement means 2c is at least partially housed in a recess 52 in the inner surface of needle retraction device 47. Additionally, engagement means 2c abut against a shoulder 51 created by recess 52 in the front of the needle retraction device 47. Thus, until engagement means 2c are moved, the piston is locked against retraction. Applicant's abovementioned advantageous construction provides a physical shield for engagement means 2c. Furthermore, because engagement means 2c are set into the body of needle retraction device 47 the likelihood of misfire due to dropping or bumping is greatly reduced.

Ryles, clearly does not teach at least partial housing of engagement means 2c in a recess in an inner surface of the needle retraction device, as recited in Applicant's claim 1. In Ryles, engagement means 27 generally abut the leading edge of the plunger 35; thus, Ryles's engagement means are fully exposed outside of plunger 35, i.e. needle retraction device. In reference to Fig 4 (shown below), Ryles specifically states:

"Each claw member 27 has a leading camming surface 32 and a trailing shoulder 33. The trailing shoulder 33 engages distal face 35 of the plunger 11 so that as the plunger is pushed in the distal direction to expel the medicament, the gripping

means gripping means 25 travels with it” Column 4, lines 59-63 (Emphasis Added)



As shown above, Ryles does not disclose the formation of any recess on an inner surface of the plunger. Therefore, the claw members 27 must abut the leading edge 35 of the plunger and are not shielded as in Applicant's invention. Thus, Applicant's claim 1 is still novel and unobvious.

It is Applicants belief that the amendments and remarks included herein clearly distinguish Applicants from Ryles. No new matter is added herein as support is found throughout the originally filed specification. The application is now believed to be in condition for allowance. Prompt issuance of Notice of Allowance is respectfully requested.

Newly added claims 13-17 are believed to be allowable for at least the reasons set forth above with respect to claims 1-8 and 11.

The Examiner is invited to contact Applicants' attorney at the below listed phone number regarding this response or otherwise concerning the present application. Applicants hereby petition for any necessary extension of time required under 37 C.F.R. 1.136(a) or 1.136(b) which may be required for entry and consideration of the present Reply. If there are any charges due with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' attorneys.

Respectfully submitted,

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